REMARKS

Claims 1-21 have been canceled.

Claims 22-30 are pending.

New claim 31 has been added. Support for this claim can be found in claim 22 and in the Specification on page 30, lines 20-23.

No new matter has been entered.

Rejections Under 35 USC § 102

The Examiner has rejected claims 22-23 and 28-29 as anticipated by Demmer et al. (US 6,001,974). The Examiner states that his rejection is based on Demmer's anticipation of steps (2) and (3) as described in instant claim 22. Specifically, the Examiner contends that Demmer et al. disclose a method of preparing a product solution by removing biological components from a human derived biological components-containing solution by subjecting the biological solution to the following two treatment steps in succession. The first step is removing a portion or all of proteins having a molecular weight to or higher than that of albumin by fractionation with a molecular sieve and retaining a portion of the solution from which the proteins have been removed (treatment performed in module 1); the Examiner contends that this step is equivalent to step (2) of claim 22. The second step is concentrating proteins by passing a solution through a porous separation membrane wherein the product solution is retained and treated portion of the solution from at least two of the three treatment steps (treatment performed in module 2); this equates to step (3) of claim 22. Applicants respectfully traverse.

Applicants first note that Demmer et al. uses ion exchange in both module 1 and module 2 of the Demmer et al. invention. Ion exchange membrane modules can separate proteins having different ionic charges even if the molecular sizes of the proteins are small enough to pass through the pore size of the membrane. For example, in anion exchange IgG4 (Pi = <6, mw = 146) would be retained by the membrane while positively charged molecules, such as IgG1 (Pi = 8-9.5, mw = 146) would pass through (see Buis et al., attached, for molecular weights and

isoelectric points). This illustrates that when the pores of the separation membrane allow molecules having a mw of 146 to pass through, if the molecule has a net negative charge, it will be retained but if it has a positive charge it will be separated out.

Demmer et al. first conduct an anion exchange procedure in module 1 and then conducts a cation exchange procedure in module 2. Demmer et al. does not concentrate albumin based on molecular weight in either case. That is, Demmer et al. does not use a molecular sieve as required by step (2) of the instant invention. Molecular sieves function by separation based on molecular weight, as evidenced by Encyclopædia Britannica and Wikipedia (see attached) and as described in the Protein Purification Wikipedia article, also attached.

In view of the above, Applicants respectfully request removal of the rejection.

Rejections Under 35 USC § 103

Demmer et al. in view of Kim et al.

The Examiner has rejected claims 24-26 and 30 as obvious over Demmer et al. in view of Kim et al. (US 7,441,666). The Examiner states that the rejection is based on the selection of steps (2) and (3) of the instant claims. The Examiner's allegations concerning the Demmer et al. reference are set forth above. Regarding Kim et al., the Examiner contends that Kim et al. uses a molecular sieve (equating to step 2 of the instant claims) and a porous separation membrane selected from cellulose and a polyamide. The Examiner concludes that it would have been obvious to use a molecular sieve and/or separation membrane as disclosed by Kim et al. in the method of Demmer et al. Applicants respectfully traverse.

As discussed above, Demmer et al. do not use a molecular sieve. While Kim et al remove albumin by employing fractionation with a molecular sieve, the skilled artisan would not have a reasonable expectation of success in simply substituting the molecular sieve used by Kim in the Demmer et al. method. Kim et al. indicate that the pore size of the membrane in contact with the loaded sample solution is about 10-100kD (column 7, lines 49-54) and that the charged portion of the membrane carries negative charges. But Demmer et al. uses Sartobind Q 100 and S 100 membranes which are strong anion and cation ion exchange membranes having a pore size of

>3μm (see Sartobind membrane description, attached). Thus, the pore size of the membrane used in the Kim et al. reference is at most about 13.8 nm, which is drastically different from the >3μm ion exchange membrane used in Demmer et al. This significant difference in pore size would prevent the separation which occurs in the anionic exchange portion of the Demmer et al. procedure that removes many of the "contaminants," such as the higher molecular weight components of plasma. Further, use of the Kim et al. membrane would not allow for cationic exchange in the Demmer et al. procedure.

Consequently, in view of the above, Applicants request removal of the rejections.

Demmer et al. in view of Comper

The Examiner rejects claim 27 as obvious over Demmer et al. in view of Comper. The Examiner's allegations regarding the Demmer et al. reference are set forth above. With respect to Comper, the Examiner states that Comper discloses the use of a blue dye in order to detect albumin in a solution during a filtration process. The Examiner concludes that it would have been obvious to the skilled artisan to add Comper's blue dye to the Demmer et al. procedure to detect the amount. Applicants respectfully traverse.

As discussed above, Demmer et al. do not use a molecular sieve. As a consequence, claim 27, which depends from claim 22 cannot be made whole by addition of Comper's blue dye disclosure. Thus, Applicants request removal of the rejection.

Conclusion

In view of the above remarks, all of the claims are submitted as defining non-obvious, patentable subject matter. Reconsideration of the rejections and allowance of the claims are respectfully requested.

If any questions arise in the above matters, please contact Applicant's representative, Susan W. Gorman (Reg. No. 47,604), in San Diego, California at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By_____

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Enclosures: Buis et al. (1996) Nephrol. Dial. Transplant 11:1113-1120
Molecular Sieve (Encyclopedia Britannica)
Molecular Sieve definintion (Wikipedia)
Protein Purification (Wikipedia)
Sartorius Sartobind Membrane Adsorbers